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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,784	07/02/2003	Ray C. Wasielewski	ORW01-GN004	5434

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EXAMINER	
SNOW, BRUCE EDWARD	
ART UNIT	**PAPER NUMBER**
3738	

DATE MAILED: 09/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

E

Office Action Summary	Application No.	Applicant(s)	
	10/612,784	WASIELEWSKI, RAY C.	
	Examiner	Art Unit	
	Bruce E. Snow	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-90* is/are pending in the application.

4a) Of the above claim(s) *17,18,38,39,80,81,89 and 90* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16,19-37,40-79 and 82-88* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/10/03; 4/6/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group 1 and Species 1 in the reply filed on 8/22/05 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Applicant elected Group 1 without traverse and Species 1 (scar tissue promoting) with traverse, however, applicant's response that the additional species is not a burden does not "specifically point out the supposed errors in the restriction requirement" and, therefore, treated as a response without traverse. A species requirement indicates that each are deemed patentable distinct inventions by the Examiner; each application can only have a single invention. Claims 17-18, 38-39, 80-81, and 89-90 are withdrawn being directed towards a non-elected Group/Species.

Information Disclosure Statement

The information disclosure statement filed 10/10/03 and 4/06/04 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, the scope of the claim is indefinite. What is being claimed, "a prosthetic device" or "constraining device"? Also, "the constraining device" lacks antecedent basis.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 54-90 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification fails to support claim 54 and especially claim 82 wherein, for example, the device promotes engagement between a first prosthetic and a first bone (such as a prosthetic cup within the acetabulum bone).

Objection to the drawings

The drawings fail to show all the constraining augments are adapted to be fastened to the "acetabular cavity within a hip bone" or "positionable about a femoral member". Additionally, please direct to the specification for support.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-16, 19-37, 40-79, 82-88 are rejected under 35 U.S.C. 102(e) as being anticipated by Ferree (2004/0024471).

Referring to at least figures 11C and 11D, Ferree teaches an augment 120 adapted to be mounted approximately to a rim of an acetabular cup assembly 117, 118 of a hip replacement prosthesis, wherein the augment assists in improving stability, at least temporarily, of a ball joint type coupling 116 between the acetabular cup assembly and a femoral stem 114, 115 of the hip replacement prosthesis; the augment being formed from a biologic and/or absorbable material.

Regarding claims 1 and 27, the augment 120 can be interpreted as being semi-annular; applicant's use of the transistionary phrase "comprising" allows for additionally structure.

Regarding claim 54, it is inherent to have multiple prosthetics 112, therefore having a plurality of constraining augments.

Regarding claim 82, the restraining device at least does not circumscribe the first or second bone components.

Claims 1-16, 19-37, 40-79, 82-88 are rejected under 35 U.S.C. 102(e) as being anticipated by McGann (6,228,122).

McGann teaches an augment 20 adapted to be mounted approximately to a rim of an acetabular cup assembly 32 of a hip replacement prosthesis, wherein the

augment assists in improving stability, at least temporarily, of a ball joint type coupling 36 between the acetabular cup assembly and a femoral stem 24 of the hip replacement prosthesis; the augment being formed from a biologic and/or absorbable material.

Note column 3, line 28, teaching "biological growth material" which is an absorbable material.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

In the alternative, claims 1-16, 19-37, 40-79, 82-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferree (2004/0024471) in view of English (4,004,300).

Referring to at least figures 11C and 11D, Ferree teaches an augment 120 adapted to be mounted approximately to a rim of an acetabular cup assembly 117, 118 of a hip replacement prosthesis, wherein the augment assists in improving stability, at least temporarily, of a ball joint type coupling 116 between the acetabular cup assembly and a femoral stem 114, 115 of the hip replacement prosthesis; the augment being formed from a biologic and/or absorbable material. However, Ferree shows the augment as being annular and one piece. English also teaches a hip replacement prosthesis in figure 3 which utilizes semi-annular augments 29 and 30 which contain the ball. It would have been obvious to one having ordinary skill in the art to have

formed the augment 120 of Ferree in multiple parts (at least two) as taught by English such that the surgeon could use a detachable ball head that can be selected from a range of sizes to suit the patient. Additionally, it would allow the surgeon the ability to implant the stem prosthesis 114 and the cup 118 separately such that the cup 118 could be impact driven into the acetabulum with the liner 117 removed thus protecting the liner.

Note keyway 35 of English.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sheldon et al (6,475,243) – note augment 392.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E. Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

bes

BRUCE SNOW
PRIMARY EXAMINER